Could that plastic device harm your patient?

BY LAURA A ALONGE. *BS*

MANY MEDICAL DEVICES contain polyvinyl chloride (PVC), a plastic polymer. Because PVC is hard and brittle at room temperature, a softener is typically added to increase the flexibility of many products, such as tubes and I.V. bags. In most medical devices, the softener is di(2-ethylhexyl)phthalate (DEHP).

Who's exposed to DEHP?

We're all normally exposed to low levels of DEHP, but a patient's exposure can increase dramatically when he receives solutions that come in contact with medical devices containing it. The amount of DEHP that leaches from the plastic depends on the solution's temperature, duration of contact with the plastic, and lipid content. Because DEHP is fat-soluble, more will leach into solutions with high lipid levels.

The FDA hasn't received reports of adverse reactions to DEHP in humans, but studies haven't ruled them out either. In animal studies, DEHP exposure has produced a range of adverse reactions, particularly in the male reproductive system and sperm production of young animals. For these reasons, the FDA Center for Devices and Radiological Health completed a safety assessment to advise health care practitioners how to reduce patients' exposure risk.

Who's most vulnerable?

The degree of risk from DEHP exposure is based on how sensitive someone is to it and how much he receives. Animal studies showed that young males were the most sensitive during the perinatal and peripubertal periods.

How much DEHP your patient receives is largely determined by how many high-risk procedures he undergoes and for how long. The more serious his illness, the more likely he is to require multiple procedures. The following ones pose the highest risks:

- transfusion (especially multiple transfusions in neonates, trauma victims, and adults undergoing extracorporeal membrane oxygenation [ECMO])
- ECMO in neonates
- multiple procedures in neonates
- hemodialysis in peripubertal boys and pregnant or lactating women
- enteral nutrition in neonates and adults, particularly total parenteral nutrition (with lipids in a PVC bag)
- heart transplantation or coronary artery bypass graft surgery.

On the bright side, infusion of crystalloid fluids such as 0.9% sodium chloride, D_5W, and lactated Ringer's solution poses little or no risk. And the amount of DEHP released from PVC bags used to store and administer pharmacy diluents poses little risk when label instructions are followed.

Playing it safe

Don't avoid performing high-risk procedures simply because DEHP could pose a health risk. Forgoing a necessary procedure is far riskier.

However, you can take some precautions. For some procedures, you can use PVC devices that don't contain DEHP or use devices made from other materials, such as ethylene vinyl acetate, silicone, polyethylene, or polyurethane. If you must use devices with DEHP, you can minimize exposure by using the freshest possible blood products stored at the lowest possible temperature or by using heparin-coated ECMO circuits.

These alternatives are most strongly recommended for high-risk procedures on male infants, peripubertal boys, and pregnant women carrying a male fetus. For other patients, the decision to use alternatives should be based on the medical advantages, drawbacks, and availability of substitute materials (see **Get the Whole Story**).

Get the whole story

You can find the complete FDA report, "Safety Assessment of Di(2-ethylhexyl)phthalate (DEHP) Released from PVC Medical Devices," at the Center for Devices and Radiological Health Web site at http://www.fda.gov/cdrh/ost/dehp-pvc.pdf.

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Although you need to support the adverse event–reporting policy of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and statements in this report are those of the author and may not reflect the views of the Department of Health and Human Services. Beverly Albrecht Callauresi, RN, BS, MPH, coordinates Device Safety.